ISRCTN10343007 https://doi.org/10.1186/ISRCTN10343007

Deferred registration - ICON Clinical (UK) Limited/Newcastle Upon Tyne Hospitals NHS Foundation Trust Code: BP45361

Submission date 01/10/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/10/2026	**Overall study status** Deferred	
Last Edited 06/11/2026	**Condition category** Other	

Plain English summary of protocol
The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date.

Contact information

Type(s)
Public, Scientific

Contact name
None - Clinical Trial Accountable

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Type(s)
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Additional identifiers

EU Clinical Trials Register (EudraCT)
2024-511110-21

Integrated Research Application System (IRAS)
1013710

Central Portfolio Management System (CPMS)
72779

Study information

Scientific Title
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Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/05/2026, Cambridge East Research Ethics Committee (2 Redman Place Stratford, London, EC20 1JQ, United Kingdom; +44 (0)2071048181; cambridgeeast.rec@hra.nhs.uk), ref: 26/EE/0070

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment

Single

Purpose
Phase I trial examining safety, tolerability, pharmacokinetics, and pharmacodynamics

Study type(s)

Health condition(s) or problem(s) studied
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Interventions
The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date.

Primary outcome(s)
1. [Outcome name] measured using [Metric or method of measurement] at [Timepoint(s)]. The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date.

Key secondary outcome(s)
1. [Outcome name] measured using [Metric or method of measurement] at [Timepoint(s)]. The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date.

Completion date
11/05/2027

Eligibility

Key inclusion criteria
The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
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Date of first enrolment
20/10/2026

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
United Kingdom

England

Austria

Netherlands

Sweden

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre
University Hospitals Plymouth NHS Trust
Derriford Hospital

Derriford Road
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England
PL6 8DH

Sponsor information

Organisation
F. Hoffman-La Roche AG

Funder(s)

Funder type

Funder Name
F. Hoffman-La Roche AG

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available